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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| KOLKER, DANIEL E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1649 | |

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/701,263 | AKIL ET AL. | |
| | Examiner | Art Unit | |
| | Daniel Kolker | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



S-10

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 (in part), 2, 5, and 6 – 10 (in part), drawn to methods of determining whether a subject has or is predisposed for a mood disorder wherein the reagent is an antibody, classified in class 435, subclass 7.1.

II. Claims 1 (in part), 3 – 4, and 6 – 10 (in part), drawn to methods of determining whether a subject has or is predisposed for a mood disorder wherein the reagent is a nucleic acid, classified in class 435, subclass 6.

III. Claims 11 (in part), 12 - 14, drawn to methods of identifying a compound, classified in class 435, subclass 7.1.

IV. Claims 11 (in part) and 15 - 16, drawn to methods of identifying a compound comprising administering the compound to an animal, classified in class 424, subclass 9.2, for example.

V. Claims 17 (in part), 18 – 19, and 22, drawn to methods of identifying a compound, classified in class 435, subclass 6.

VI. Claims 17 (in part) and 20 – 21, drawn to methods of identifying a compound comprising administering the compound to an animal, classified in class 424, subclass 9.2, for example.

VII. Claims 23 – 24, drawn to methods of treating a mood disorder, classification dependent upon structure.

VIII. Claims 26 – 27, drawn to methods of treating disorders by administering a polypeptide, classified in class 514, subclass 2, for example.

IX. Claims 28 - 29, drawn to methods of treating disorders by administering a nucleic acid, classified in class 514, subclass 44.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions require different starting materials that cannot be substituted one for the other. Group I requires antibodies, which bind to proteins, whereas group II requires nucleic

acids, which bind to other nucleic acids. Furthermore, search for Group I is not coextensive with search for group II as the former requires searching for antibodies while the latter requires searching for nucleic acids. Thus there would be a burden if the two inventions were to be considered together.

Inventions I and II are not related to any of Inventions III - IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Groups I and II are methods of determining if a subject has or is predisposed to a disorder. These methods have different steps, goals, and starting materials than the methods of Groups III – IX. For example, Groups I and II each require obtaining a sample from a subject which is not required for any of the other methods. Since consideration of either Group I or II requires search for this step, which is not required for consideration of Groups III – IX, considering either group I or II with any of groups III – IX would be burdensome for the examiner.

Invention III is not related to Invention IV and Invention V is not related to Invention VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Groups IV and VI each require different starting materials and steps than groups III and V, respectively. Groups IV and VI require animals, and require the administration of compounds to animals. Animals are not required for groups III and V. Consideration of Group IV or VI requires searching for the administration step which is not required for groups III and V, so consideration of group III with group IV or group V with group VI would be burdensome for the examiner.

Inventions III and IV are not related to Inventions V and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods with different starting materials. Groups III and IV require polypeptides, which are not required for either Group V or VI, as these require cells comprising nucleic acids. Since the starting materials required for the different groups are different, searches required for them are not coextensive and thus there would be a serious burden if either Group III or IV were to be considered with either of Group V or VI.

Inventions III – VI are not related to any of Inventions VII – IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups III – VI are methods of identifying compounds which all require contacting compounds with either a polypeptide or a cell comprising a nucleic acid. This step is not required for any of Groups VII – IX. Because the contacting step is not required for Groups VII – IX, the searches for Groups III – VI are not coextensive with the searches for Groups VII – IX, so there would be a serious burden if any of the former groups were to be examined with any of the latter.

Inventions VII, VIII, and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions all require different starting materials. Group VII requires a compound of undisclosed structure, group VIII requires administration of a polypeptide, and Group IX requires administration of a nucleic acid. Because the starting materials are different, searches required for each invention are non-overlapping and thus it would be burdensome to consider any two of these groups together.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and divergent search requirements, restriction for examination purposes as indicated is proper.

***Requirement for Further Restriction***

4. All groups are drawn to a plethora of nucleic acid sequences which appear in tables 2 – 4. In response to this restriction requirement, applicant is required to elect a single nucleic acid to which prosecution on the merits will be restricted. This additional restriction is proper because each nucleic acid sequence is a different chemical entity with unique physical and biochemical properties. Furthermore consideration of each nucleic acid sequence requires a separate search, so consideration of more than one nucleic acid sequence would be very burdensome for the examiner.

Applicant is advised that this is not a species election, but rather an additional requirement for restriction.

***Requirement for Election of Species***

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

Mood disorders

a) bipolar disorder I

b) bipolar disorder II

c) major depression disorder

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 – 7, 9 – 13, 15 – 21, 23, 25 – 26, and 28 – 29 are generic with respect to mood disorders.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker, Ph.D.
September 9, 2005

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER